



Docket No.: PF-0163-2 DIV

Response Under 37 C.F.R. 1.116 - Expedited Procedure
Examining Group 1642

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Bandman et al.

Title: NOVEL HUMAN SELENIUM-BINDING PROTEIN

Serial No.: 09/841,758

Filing Date: April 24, 2001

Examiner: Yaen, C.

Group Art Unit: 1642

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RESPONSE TO FINAL OFFICE ACTION

Sir:

In response to the Final Office Action dated **March 13, 2003** (Final Office Action), Applicants request reconsideration of the above-referenced patent application in view of the following remarks.

1. (As Once Amended) An isolated polypeptide selected from the group consisting of:
 - a) a polypeptide comprising the amino acid sequence of SEQ ID NO:1,
 - b) a polypeptide comprising a naturally-occurring amino acid sequence at least 96% identical to the amino acid sequence of SEQ ID NO:1,
 - c) a biologically-active fragment of a polypeptide having the amino acid sequence of SEQ ID NO:1, and
 - d) an immunogenic fragment of a polypeptide having the amino acid sequence of SEQ ID NO:1.
2. (As Once Amended) An isolated polypeptide of claim 1, comprising the amino acid sequence of SEQ ID NO:1.
3. (Reiterated) An isolated polynucleotide encoding a polypeptide of claim 1.
4. (Reiterated) A recombinant polynucleotide comprising a promoter sequence operably linked to a polynucleotide of claim 3.
5. (Reiterated) A cell transformed with a recombinant polynucleotide of claim 4.
6. (Reiterated) A method for producing a polypeptide of claim 1, the method comprising:
 - a) culturing a cell under conditions suitable for expression of the polypeptide, wherein said cell is transformed with a recombinant polynucleotide, and said recombinant polynucleotide comprises a promoter sequence operably linked to a polynucleotide encoding the polypeptide of claim 1, and
 - b) recovering the polypeptide so expressed.
7. (Reiterated) An isolated antibody which specifically binds to a polypeptide of claim 1.

8. (Reiterated) An isolated polynucleotide comprising a sequence selected from the group consisting of:

- a) a polynucleotide sequence of SEQ ID NO:2,
- b) a naturally-occurring polynucleotide sequence having at least 90% sequence identity to the sequence of SEQ ID NO:2,
- c) a polynucleotide sequence complementary to a),
- d) a polynucleotide sequence complementary to b) and
- e) a ribonucleotide equivalent of a)-d).

9. (Reiterated) An isolated polynucleotide comprising at least 60 contiguous nucleic acids of claim 8.

10. (Reiterated) A method for detecting a target polynucleotide in a sample, said target polynucleotide having a sequence of a polynucleotide of claim 8, the method comprising:

- a) hybridizing the sample with a probe comprising at least 20 contiguous nucleotides comprising a sequence complementary to said target polynucleotide in the sample, and which probe specifically hybridizes to said target polynucleotide, under conditions whereby a hybridization complex is formed between said probe and said target polynucleotide or fragments thereof, and
- b) detecting the presence or absence of said hybridization complex, and, optionally, if present, the amount thereof.

11. (Reiterated) A method of claim 10, wherein the probe comprises at least 60 contiguous nucleotides.

12. (Reiterated) A method for detecting a target polynucleotide in a sample, said target polynucleotide having a sequence of a polynucleotide of claim 8, the method comprising:

- a) amplifying said target polynucleotide or fragment thereof using polymerase chain reaction amplification, and

b) detecting the presence or absence of said amplified target polynucleotide or fragment thereof, and, optionally, if present, the amount thereof.

13. (Reiterated) A composition comprising a polypeptide of claim 1 and an acceptable excipient.

14. (As Once Amended) A composition of claim 13, wherein the polypeptide comprises the amino acid sequence of SEQ ID NO:1.

15. (Reiterated) A method for screening a compound for effectiveness as an agonist of a polypeptide of claim 1, the method comprising:

- a) exposing a sample comprising a polypeptide of claim 1 to a compound, and
- b) detecting agonist activity in the sample.

16. (Reiterated) A method for screening a compound for effectiveness as an antagonist of a polypeptide of claim 1, the method comprising:

- a) exposing a sample comprising a polypeptide of claim 1 to a compound, and
- b) detecting antagonist activity in the sample.

17. (Reiterated) A method for screening a compound for effectiveness in altering expression of a target polynucleotide, wherein said target polynucleotide comprises a polynucleotide sequence of claim 8, the method comprising:

- a) exposing a sample comprising the target polynucleotide to a compound, under conditions suitable for the expression of the target polynucleotide,
- b) detecting altered expression of the target polynucleotide, and
- c) comparing the expression of the target polynucleotide in the presence of varying amounts of the compound and in the absence of the compound.

18. (Reiterated) A method for assessing toxicity of a test compound, said method comprising:

- a) treating a biological sample containing nucleic acids with the test compound;
- b) hybridizing the nucleic acids of the treated biological sample with a probe comprising at least 20 contiguous nucleotides of a polynucleotide of claim 8 under conditions whereby a specific hybridization complex is formed between said probe and a target polynucleotide in the biological sample, said target polynucleotide comprising a polynucleotide sequence of a polynucleotide of claim 8 or fragment thereof;
- c) quantifying the amount of hybridization complex; and
- d) comparing the amount of hybridization complex in the treated biological sample with the amount of hybridization complex in an untreated biological sample, wherein a difference in the amount of hybridization complex in the treated biological sample is indicative of toxicity of the test compound.

19. (Reiterated) A diagnostic test for a condition or disease associated with the expression of HSEBP in a biological sample comprising the steps of:

- a) combining the biological sample with an antibody of claim 7, under conditions suitable for the antibody to bind the polypeptide and form an antibody: polypeptide complex; and
- b) detecting the complex, wherein the presence of the complex correlates with the presence of the polypeptide in the biological sample.

20. (Reiterated) The antibody of claim 7, wherein the antibody is:

- (a) a chimeric antibody;
- (b) a single chain antibody;
- (c) a Fab fragment;
- (d) a F(ab')₂ fragment; or
- (e) a humanized antibody.